

**IN THE UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF DELAWARE**

NIPPON SHINYAKU CO. LTD.,	)	
	)	
Plaintiff,	)	
	)	C.A. No. 21-1015 (GBW)
v.	)	
	)	<b>DEMAND FOR JURY TRIAL</b>
SAREPTA THERAPEUTICS, INC.,	)	
	)	
Defendant.	)	
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SAREPTA THERAPEUTICS, INC. and THE	)	
UNIVERSITY OF WESTERN AUSTRALIA	)	<div style="background-color: black; width: 100%; height: 1.2em;"></div>
	)	
Defendant/Counter Plaintiffs,	)	<div style="background-color: black; width: 100%; height: 1.2em;"></div>
	)	
v.	)	
	)	
NIPPON SHINYAKU CO., LTD.	)	
and NS PHARMA, INC.	)	
	)	
Plaintiff/Counter Defendants.	)	

**PLAINTIFF’S MEMORANDUM OF LAW IN SUPPORT OF ITS MOTION FOR  
PARTIAL SUMMARY JUDGMENT NO. 4 -  
NO ANTICIPATION**

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**Dated: December 11, 2023**

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## I. INTRODUCTION

Sarepta Therapeutics, Inc. and the University of Western Australia (together, “Sarepta”) contend that claim 3 of the ’092 Patent, claim 2 of the ’461 Patent, and claims 1-4 of the ’217 Patent are anticipated by U.S. Patent Publication No. 2010/0168212 A1 (“’212 Popplewell”). Each of claim 3 of the ’092 Patent, claim 2 of the ’461 Patent, and claims 1-4 of the ’217 Patent requires that the 5’-end of the claimed PMO is attached to a triethylene glycol (“TEG”) group. It is undisputed that ’212 Popplewell does not disclose a PMO with the claimed 5’-TEG limitation.

But this has not stopped Sarepta from arguing that ’212 Popplewell anticipates those claims under 35 U.S.C. § 102. In support of this contention, Sarepta offers the testimony of Dr. Steven Dowdy who opined that “[REDACTED]” Ex. 1 (Opening Expert Report of Steven F. Dowdy, Ph.D. (“Dowdy Opening”)) ¶ 335.

Sarepta (and its expert) have misapplied the law of anticipation. Anticipation requires a single prior art reference that discloses “all elements of the claim within the four corners of the document, [and] also disclose[s] those elements ‘arranged as in the claim.’” *Net MoneyIN, Inc. v. VeriSign, Inc.*, 545 F.3d 1359, 1369 (Fed. Cir. 2008). The contention that a POSA can supply a missing limitation with the general knowledge in the art is not anticipation. *Nidec Motor Corp. v. Zhongshan Broad Ocean Motor Co. Ltd.*, 851 F.3d 1270, 1274-75 (Fed. Cir. 2017) (the “at once envisage” test “does not permit . . . fill[ing] in missing limitations simply because a skilled artisan would immediately envision them.”). Thus, Sarepta’s anticipation argument as to claim 3 of the ’092 Patent, claim 2 of the ’461 Patent, and claims 1-4 of the ’217 Patent fails as a matter of law.

## II. NATURE AND STAGE OF THE PROCEEDINGS

NS incorporates by reference its statement regarding the nature and stage of the proceedings from its Motion for Partial Summary Judgment No. 1.

### **III. CONCISE STATEMENT OF FACTS**

NS incorporates by reference its concise statement of undisputed facts (“SOF”) filed contemporaneously herewith.

### **IV. SUMMARY OF THE ARGUMENT**

The Court should grant partial summary judgment of no anticipation of claim 3 of the ’092 Patent, claim 2 of the ’461 Patent, and claims 1-4 of the ’217 Patent in favor because Sarepta improperly uses the knowledge of a POSA to fill in a limitation that is missing from ’212 Popplewell.

### **V. LEGAL STANDARD**

NS incorporates by reference its legal standard section from its Motion for Partial Summary Judgment No. 1.

### **VI. ARGUMENT**

Summary judgment of no anticipation is appropriate where “the evidence does not support express or inherent disclosure” of one or more claim limitations. *SRI Int’l, Inc. v. Cisco Sys., Inc.*, 918 F.3d 1368, 1379 (Fed. Cir. 2019) (“Because the evidence does not support express or inherent disclosure of direct examination of packet data, we conclude that the district court did not err in holding that there was no genuine issue of fact regarding whether EMERALD 1997 disclosed analyzing the specific enumerated types of network traffic data recited in the claims.”). “Anticipation requires that a single prior art reference disclose each and every limitation of the claimed invention, either expressly or inherently.” *Id.* at 1378.<sup>1</sup> In addition to disclosing each element, the reference “must also disclose those elements ‘arranged as in the claim.’” *Net MoneyIN, Inc.*, 545 F.3d at 1369.

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<sup>1</sup> Sarepta/UWA did not advance a theory of inherent anticipation.

Dr. Dowdy [REDACTED]

[REDACTED] Ex. 13 (Dowdy Dep.) at 123:25–124:3 ([REDACTED]  
[REDACTED]; Ex. 2 (Reply  
Expert Report of Steven F. Dowdy, Ph.D. (“Dowdy Reply”)) ¶ 50 (agreeing that the “[REDACTED]  
[REDACTED]”). Because Popplewell ’212 lacks  
any disclosure of the TEG medication, its disclosures are insufficient as a matter of law to establish  
anticipation. *See SRI Int’l, Inc. v. Cisco Sys., Inc.*, 930 F.3d 1295, 1306 (Fed. Cir. 2019)  
(anticipation requires disclosure of “each and every limitation”); *Plexxikon Inc. v. Novartis  
Pharms. Corp.*, No. 17-04405-HSG, 2021 WL 707653, at \*6 (N.D. Cal. Feb. 23, 2021) (no  
“genuine dispute that Example 61 does not anticipate the asserted claims” where expert “confirms  
that Example 61 meets the limitations of the asserted claims ‘with [the] exception’ of the missing  
fluorine”).

Dr. Dowdy nevertheless opines that claim 3 of the ’092 Patent, claim 2 of the ’461 Patent,  
and claims 1-4 of the ’217 Patent are anticipated by ’212 Popplewell because “[r]eading  
Popplewell US ’212 in light of the general knowledge in the art, a POSA as of August 31, 2011  
would at once envisage the TEG modification.” Ex. 1 (Dowdy Opening) ¶ 335; *id.* ¶ 336 (“A  
limited number of 5’-end modifications for PMOs were known in the art, including the TEG  
modification” so “[a] POSA would at once envisage this modification upon reading Popplewell  
US ’212.”); ¶¶ 353-354, 362-363; *see also* Ex. 2 (Dowdy Reply) ¶ 51 (“A POSA reading  
Popplewell US ’212 and its reference to ‘PMO’ would at once envisage these 5’-end modifications,  
including the TEG modification.”).

But Dr. Dowdy misapplies the “at once envisage” test for anticipation. As the Federal  
Circuit explained in *Nidec Motor Corp.*:

*Kennametal* does not stand for the proposition that a reference missing a limitation can anticipate a claim if a skilled artisan viewing the reference would “at once envisage” the missing limitation. Rather, *Kennametal* addresses whether the disclosure of a limited number of combination possibilities discloses one of the possible combinations. . . . *Kennametal* does not permit the Board to fill in missing limitations simply because a skilled artisan would immediately envision them.

851 F.3d at 1274-75; *see also UCB, Inc. v. Actavis Lab ’ys UT, Inc.*, 65 F.4th 679, 688 (Fed. Cir. 2023) (“*Kennametal* does not stand for the proposition that a reference missing a limitation can anticipate a claim if a skilled artisan viewing the reference would ‘at once envisage’ the missing limitation.”) (citation omitted); *Galderma Lab ’ys, L.P. v. Teva Pharms. USA, Inc.*, 799 F. App’x 838, 845 (Fed. Cir. 2020) (“[D]istrict court was not permitted ‘to fill in missing limitations simply because a skilled artisan would immediately envision them.’”) (citation omitted); *Plexxikon Inc.*, 2021 WL 707653, at \*6 (rejecting anticipation theory based on argument “that a person of ordinary skill in the art would ‘at once envision’ Example 61 with the missing fluorine because Formula (I) ‘provides a finite number of limited alternatives’”) (citation omitted). Yet this is precisely what Dr. Dowdy does—he relies on the knowledge of the POSA to supply the 5’-TEG limitation that is undisputedly missing from ’212 Popplewell. That is insufficient as a matter of law to establish anticipation.

Accordingly, there is no genuine dispute that ’212 Popplewell does not anticipate claim 3 of the ’092 Patent, claim 2 of the ’461 Patent, and claims 1-4 of the ’217 Patent by ’212 Popplewell.

## VII. CONCLUSION

For the foregoing reasons, the Court should grant partial summary judgment of no anticipation for claim 3 of the ’092 Patent, claim 2 of the ’461 Patent, and claims 1-4 of the ’217 Patent.

Dated: December 11, 2023

Respectfully submitted,

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